

EXHIBIT 2

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from

to

Commission File Number: 001-39724

LIQUIDIA CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware

85-1710962

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

419 Davis Drive, Suite 100, Morrisville, North Carolina

27560

(Address of Principal Executive Offices)

(Zip Code)

Registrant's telephone number, including area code: **(919) 328-4400**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value per share	LQDA	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐

Accelerated Filer ☐

Non-accelerated Filer ☒

Smaller Reporting Company ☒

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of common stock held by non-affiliates of the registrant on June 30, 2024 which was the last business day of the registrant's most recently completed second fiscal quarter, was \$685,662,096 based on a \$12.00 closing price per share as reported on the Nasdaq Capital Market.

As of March 10, 2025, there were 85,298,537 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Liquidia Corporation Definitive Proxy Statement with respect to the 2025 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2024 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated therein. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, each document incorporated by reference herein is deemed not to be filed as part hereof.

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In clinical studies required for approval, YUTREPIA has proven to be safe, well-tolerated and effective regardless of a patient's previous exposure to treprostinil. Prostacyclin-naïve patients achieved comparable dosing to the transition patients within the first two months of treatment. Patients on a stable dose of Tyvaso successfully transitioned to YUTREPIA while maintaining or improving clinical outcomes as measured by exploratory endpoints. The combination of data from both patient groups provide confidence that a physician may prescribe YUTREPIA across a continuum of PAH and PH-ILD patients.

We have developed YUTREPIA under the 505(b)(2) regulatory pathway using the nebulized form of treprostinil, Tyvaso, as the reference listed drug. This regulatory pathway allows us to rely in part on the FDA's previous findings of efficacy and safety of Tyvaso and the active ingredient treprostinil. We submitted NDA for YUTREPIA in January 2020. The FDA conducted on-site pre-approval inspections of two U.S. manufacturing facilities: our Morrisville, North Carolina facility and the facility of the third-party provider of encapsulation and packaging services for YUTREPIA in August 2021 and October 2021, respectively. In November 2021, the FDA issued a tentative approval of YUTREPIA which indicated that the NDA had met all the requirements for final approval but cannot yet be marketed. In July 2023, we filed an amendment to our NDA to add PH-ILD to the labeled indications for YUTREPIA. The FDA issued a tentative approval of the amended NDA for both PAH and PH-ILD in August 2024. Final FDA approval of the NDA for YUTREPIA is delayed until the expiration on May 23, 2025 of New Clinical Investigation exclusivity that was granted to Tyvaso DPI.

Final FDA approval and launch may be impacted by litigation commenced by United Therapeutics in which it may seek to enjoin approval and launch of YUTREPIA as described further in *Item 3 Legal Proceedings*. The FDA's tentative approval can be subject to change based on new information that may come to FDA's attention between such time as the tentative and final approval. A new drug product may not be marketed until the date of final approval.

Our NDA submission was based in part upon the results of our pivotal, open-label Phase 3 clinical trial, Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, for YUTREPIA ("INSPIRE"). The primary objective of the INSPIRE study was to evaluate the long-term safety of YUTREPIA with a primary endpoint to assess safety and tolerability through Month 2. The study enrolled patients who have either (a) been under stable treatment with Tyvaso (nebulizer-delivered treprostinil) for at least three months and transitioned to YUTREPIA under the protocol ("Transition patients"), or (b) patients who had been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and then had their treatment regimen supplemented with YUTREPIA under the protocol ("Prostacyclin Naïve patients"). Of the 121 patients enrolled in the study, 55 were Transition patients and 66 were Prostacyclin Naïve patients. Transition patients started at a dose comparable to their prior nebulized treprostinil dose and were titrated to higher doses as warranted by their clinical disease. Prostacyclin Naïve patients started on a dose of 26.5 mcg of YUTREPIA, with most (>80%) titrating to a 79.5 mcg dose or higher within the first two months of treatment.

YUTREPIA was observed to be well-tolerated and treatment-emergent adverse events ("TEAEs") were mostly mild to moderate in nature at Month 2 up to doses of 159 mcg, the highest dose studied for the primary endpoint. We continued to treat patients who chose to remain on YUTREPIA beyond the Month 2 timepoint. At the completion of the INSPIRE study, the patient with the longest duration of treatment had been on YUTREPIA therapy for 18 months and the highest dosing reached in the INSPIRE study was 212 mcg of treprostinil given four times per day. Patients from INSPIRE had the option of rolling into the LTI-302 extension study to remain on treatment. Patients in LTI-302 continued to titrate doses upwards as needed with no observed maximum tolerated dose and the highest dose observed to date being 291.5 mcg.

Our NDA submission also includes results from pharmacokinetic ("PK") studies in healthy volunteers indicating that the single-capsule dose of 79.5 mcg YUTREPIA provides comparable PK with 9 bps of Tyvaso (54 mcg). For reference, the target dose of Tyvaso is 9 to 12 bps, 4 times daily. Clinical results from the PK, pivotal and extension studies of YUTREPIA have been presented at various international scientific meetings such as the American Thoracic Society (ATS), International Society of Heart Lung Transplantation (ISHLT), Pulmonary Vascular Research Institute (PVRI), American College of Chest Physicians (ACCP) from 2019 through 2024.